

**PATENT COOPERATION TREATY**  
**PCT**  
**INTERNATIONAL PRELIMINARY EXAMINATION REPORT**  
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 021040PC/IDJ	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).	
International Application No. <b>PCT/AU2003/001187</b>	International Filing Date (day/month/year) 10 September 2003	Priority Date (day/month/year) 20 September 2002
International Patent Classification (IPC) or national classification and IPC Int. Cl. <sup>7</sup> A61B 17/32		
Applicant OCCUPATIONAL & MEDICAL INNOVATIONS LTD et al		

This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.


2. This REPORT consists of a total of 5 sheets, including this cover sheet.

- ☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 3 sheet(s).

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 5 April 2004	Date of completion of the report 17 January 2005
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer  <b>DAVID MELHUISE</b> Telephone No. (02) 6283 2426

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/AU2003/001187

**I. Basis of the report****1. With regard to the elements of the international application:\***

- ☐ the international application as originally filed.
- ☒ the description, pages 1 - 17, as originally filed,  
pages , filed with the demand,  
pages , received on with the letter of
- ☒ the claims, pages , as originally filed,  
pages , as amended (together with any statement) under Article 19,  
pages , filed with the demand,  
pages 18 - 20, received on 13 May 2004 with the letter of 13 May 2004
- ☒ the drawings, pages 1/17 - 17/17, as originally filed,  
pages , filed with the demand,  
pages , received on with the letter of
- ☐ the sequence listing part of the description:  
pages , as originally filed  
pages , filed with the demand  
pages , received on with the letter of

**2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.**

These elements were available or furnished to this Authority in the following language which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

**3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:**

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

**4. ☐ The amendments have resulted in the cancellation of:**

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/fig.

**5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\***

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

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PCT/AU2003/001187

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims 1 - 12	YES
	Claims 13, 14	NO
Inventive step (IS)	Claims 2 - 12	YES
	Claims 1, 13, 14	NO
Industrial applicability (IA)	Claims 1 - 14	YES
	Claims	NO

**2. Citations and explanations (Rule 70.7)****NOVELTY (N) Claims 13 and 14:**

D1 - US 5868771 A

D1 discloses the features of claims 13 and 14. Column 4 line 25 to column 5 line 58 of D1 describes a safety scalpel comprising a handle, a blade and a guard wherein the blade is retained in the guard and released when the blade is attached to the handle. Also disclosed is a safety catch to prevent excessive retraction of the guard, this being item 225 in figure 7. This catch is positioned on a forward part of the guard and comprises a projection. See also column 6 lines 57 to 60. Therefore all features of claim 13 are disclosed by D1 and hence claim 13 is not novel.

D1 also discloses the features of claim 14, which defines the same features as claim 13 except for location means to positively locate the guard in the extended and retracted positions instead of the safety catch of claim 13. The means to locate the guard in the extended position is the thumb button 215, which must be pressed with the thumb to withdraw the guard. See column 5 lines 9 to 15. Once in the retracted position, the guard is held in place by tip 221 engaging with ridges 102. See column 5 lines 16 to 22. Therefore claim 14 is also not novel because D1 discloses all the features of claim 14.

**INVENTIVE STEP (IS) Claims 1, 13 and 14:**

D2 - US 6058607 A

D3 - WO 2001/005312 A1

D4 - EP 555196 A1

D5 - WO 2001/074257 A1

D6 - US 3905101 A

Claims 13 and 14: As per novelty above.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

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PCT/AU2003/001187

**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

**Continuation of Box V**

Claim 1: A removable tab on the guard of a safety knife is known in the art. See item 74 in figure 50 of D2. The combination of the tab of D2 with the scalpel of D1, as would be obvious to a person skilled in the art, includes all the features of claims 1,6,7 and 9-11. Therefore these claims lack an inventive step.

Claims 13 and 14: The differences between D3 and claims 13 and 14 involve features that are well known in the art. These differences are the safety catch of claim 13 and the location means of claim 14, both of which are disclosed by D4 to D6. For example, D5 discloses location means comprising projections 34 and 36 in figure 1 which fit into hollow 35 in cover 10 to locate the guard in the extended and retracted positions. The hollow 35 in figure 3 may be a projection which fits into hollows 34 and 36. In this case the projection 35 would be the safety catch of claim 13 comprising a projection on the forward part of the guard. The combination of D3 and D5, as would be obvious to a person skilled in the art, results in a safety scalpel that has all the features of claims 13 and 14. Therefore claims 13 and 14 lack an inventive step.

Similarly for the combination of D3 and D4, which also renders claims 13 and 14 non-inventive.

The combination of D3 and D6 renders claims 14 non-inventive.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

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PCT/AU2003/001187

**VIII. Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

1. Claim 1 is not fully supported by the description because it does not define the function of the removable tab. The description states that the tab results in "an improvement to the method of attachment of the blade assembly to the handle" (page 13 lines 11-12), yet claim 1 merely defines any grippable tab that is attached to the guard.
2. Claims 12, 13 and 14 lack clarity because they define a time when the "assembly is being attached to the handle" (eg. claim 12 line 6). This conflicts with lines 1 and 2 of the claims, which define that the handle is part of the assembly.
3. Claim 14 lacks clarity because
  - a) there is no antecedent for "the extended position" or "the retracted position" (both line 9).
  - b) it is not clear what the guard is located relative to.